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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,625	06/22/2001	Yoshihiko Makino	JG-YY-5090 / 500569.20069	7410

7590 05/03/2002
REED SMITH LLP
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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/03/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/887,625

Applicant(s)

MAKINO ET AL.

Examiner

Arun Chakrabarti

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

Art Unit: 1634

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as indefinite because the instantly claimed methods lacks final process steps that clearly relates back to the preamble. For the method of claim 1, the preamble of the instantly claimed method is drawn to a method for detecting nucleic acid fragments in plural samples while the final process step is that of comparing the electric current detected in the former and latter detecting procedure and it is thus unclear as to whether the instantly claimed method is drawn to a process for detecting nucleic acid fragments in plural samples or rather comparing the electric current detected in the former and latter detecting procedure. Method claim requires a last step or phrase in the last step that states the accomplishments of the goals for the method which were stated in the method's preamble. Claim 1 lacks such a last step and is confusing because the additional method step is not sufficiently set forth. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active

Art Unit: 1634

fashions. See Ex parte Erlich, 3 USPQ2d1011, p.1011 (Bd. Pat. Applicant. Int. 1986). It is suggested that an amended claim more clearly describing the intended steps be submitted.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Mathies et al. (U.S. Patent 6,361,671 B1) (March 26, 2002).

Mathies et al teach a method of detecting nucleic acid fragments in plural samples (Abstract) which comprises the steps of:

a) attaching an electroconductive label to nucleic acid fragments in one sample and attaching another electroconductive label to nucleic acid fragments in another sample, the former electroconductive label and the latter electroconductive label having oxidation-reduction potentials differing from each other (Claims 8, and 26-42 and Column 10, lines 14-26);

b) preparing a mixture of the samples containing nucleic acid fragments to which electroconductive labels are attached (Claims 8, and 26-42 and);

Art Unit: 1634

c) bringing the mixture into contact with an electroconductive microarray having plural electrodes onto which probe molecules complementary to the nucleic acid fragments are fixed, so that hybridization between the nucleic acid fragments having electroconductive labels and the probe molecules on the electroconductive microarray can proceed to form hybrid structures on the electrodes (Column 8, line 55 to Column 9, line 6 and Column 10, lines 46-55 and Figure 1);

d) applying to the electrode an electric potential corresponding to the oxidation-reduction potential of the former electroconductive label and detecting on the electrode an electric current flowing along the hybrid-structure (Figures 4-5 and 8-9 and Claim 41);

e) applying to the electrode an electric potential corresponding to the oxidation-reduction potential of the latter electroconductive label and detecting on the electrode an electric current flowing along the hybrid-structure (Figures 4-5 and 8-9)

and

f) comparing the electric current detected in the former detecting procedure and the electric current detected in the latter detecting procedure (Figures 4-5 and 8-9).

Mathies et al teach a method, wherein the probe molecules are nucleic acid fragments (Claims 26-42 and column 10, line 14 to column 11, line 45).

Mathies et al teach a method, wherein the probe molecules are peptide nucleic acid fragments (Column 11, lines 22-26 and Column 12, lines 29-36).

Art Unit: 1634

Mathies et al teach a method, wherein the oxidation-reduction potential of the latter electroconductive label differs from the oxidation-reduction potential of the former electroconductive label by at least 50 mV (Figures 4A and 4B and Column 7, lines 60-63).

Mathies et al teach a method, wherein the oxidation-reduction potential of the former electroconductive label and the oxidation-reduction potential of the latter electroconductive label both are in the range of 0 to 800 mV (Figures 4A and 4B and Column 7, lines 60-63).

Mathies et al teach a method, wherein the detection of electric current on the electrodes are conducted by differential pulse voltamography (Figures 4A and 4B and Column 8, lines 30-40).

Mathies et al inherently teach a method, wherein one sample is obtained from normal cells and another sample is obtained from abnormal cells corresponding to the normal cells (Claims 41 and 42 and Column 3, lines 38-53).

Mathies et al inherently teach a method, wherein one sample is obtained from wild strain and another sample is mutant thereof (Claims 41 and 42 and Column 3, lines 38-53). This inference is deduced from the fact that polymorphisms and mutations are detected compared to normal cells or wild strain.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703)

Art Unit: 1634

306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

April 2, 2002


ARUN K. CHAKRABARTI
PATENT EXAMINER


W. Gary Jones
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